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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/677,976   | 10/02/2000  | Michael E. Kafrissen | ORT-1316            | 7964             |
| 7590   | 07/25/2006  |                      | EXAMINER            |                  |
| Philip S Johnson Esq<br>Johnson & Johnson<br>One Johnson & Johnson Plaza<br>New Brunswick, NJ 08933-7003 |             |                      | CHOI, FRANK I       |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1616                |                  |

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



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| APPLICATION NO./<br>CONTROL NO. | FILING DATE | FIRST NAMED INVENTOR /<br>PATENT IN REEXAMINATION | ATTORNEY DOCKET NO. |
|---------------------------------|-------------|---|---------------------|

EXAMINER

ART UNIT      PAPER

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Commissioner for Patents

NOTICE OF NON-RESPONSIVE AMENDMENT

Amended claim 21, previously presented claims 22, 23 which are dependent on claim 21 and newly submitted claim 23 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The previous method was directed to reducing the risk of cervical dysplasia or cervical carcinoma in subjects for whom oral contraceptives were indicated for prevention of pregnancy, whereas, the claims, as amended, are now directed to reducing the risk of neural tube defects.

In the instant case, the prior claims and claims, as amended, are unrelated. The claims are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions, as indicated above, do not appear to be disclosed in the Specification as capable of use together (nor can they be used together as a subject in which the risk of neural tube defects is reduced for whom oral contraceptives is indicated and also is afflicted with neural tube defects at a higher-than-normal incidence does not exist; see discussion below) and they have different designs, modes of operation and effects as the folic acid in the prior claims is directed toward cervical cells of women capable of becoming pregnant, whereas, the folic acid in the present claims are directed toward neural tube cells in the developing embryo or fetus.

Alternatively, the prior claims and the presently amended claims are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the claims do not overlap in scope in that the claims as worded require that the reduction in risk of neural tube defects occurs in a subject for whom an oral contraceptive is indicated for preventing pregnancy and is also afflicted with neural tube defects at a higher-than-normal incidence. Said subject cannot exist as the risk of neural tube defects occurs in developing embryos or fetuses, whereas, the subject for whom an oral contraceptive is indicated is a woman capable of becoming pregnant. For the same reasons, the prior claims and the presently amended claims are not obvious variants and are not capable of use together. Further, the presently amended claims have a materially different design, mode of operation, function or effect as indicated above.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search, in that the prior claims did not require search of neural tube defects (see MPEP § 808.02), restriction for examination purposes as indicated is proper. As such, in light of the above, prosecution of the claims, as presently amended, would constitute an undue burden on examiner.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21-24 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The amendment filed on 5/3/2006 which in effect canceled all claims drawn to the elected invention by deleting all limitations related to cervical dysplasia and cervical carcinoma and presented only claims drawn to a non-elected invention is non-responsive (MPEP § 821.03). The remaining claims are not readable on the elected invention as indicated above.

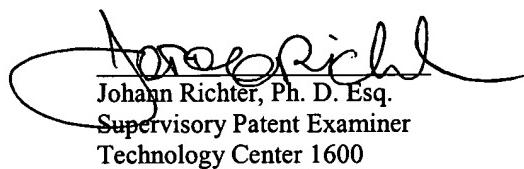
Since the above-mentioned amendment appears to be a bona fide attempt to reply, applicant is given a TIME PERIOD of ONE (1) MONTH or THIRTY (30) DAYS, whichever is longer, from the mailing date of this notice within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD UNDER 37 CFR 1.136(a) ARE AVAILABLE.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Dr. Johann Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi  
Patent Examiner  
Technology Center 1600  
July 18, 2006



Johann Richter, Ph. D. Esq.  
Supervisory Patent Examiner  
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